



UNITED STATES
PATENT AND
TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
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In re Application of Suzanne Cory et al. :
Serial No.: 09/508,832 :
Filed: July 10, 2000 : PETITION DECISION
Attorney Docket No.: 017227/0159 :

This is in response to applicants' petition, filed October 11, 2002 under 37 CFR 1.181, which is being treated as a petition under 37 CFR 1.144, requesting withdrawal of the restriction requirement set forth by the examiner.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 as the National Stage of PCT/AU98/00772, filed September 17, 1998, which claims priority to Australian applications PO 9263 and PO 9373, filed September 17, 1997 and September 24, 1997, respectively. The application, as filed, contained claims 1-61. In a first Office action mailed December 14, 2001, the examiner set forth a restriction / lack of unity requirement under 35 U.S.C. 121 and 372 dividing the claims into 22 groups.

In the response filed July 16, 2002, applicants elected Group V, drawn to nucleic acid molecules encoding a polypeptide having one or more identifying characteristics of SEQ ID No: 10 or a derivative or homologue thereof having the ability to cause apoptosis. Applicants also amended the claims, attempting to overcome the prior art cited in the restriction requirement. Applicants traversed the restriction on essentially the same grounds presented in the instant petition.

On August 23, 2002 a second examiner mailed a first Office action on the merits. The restriction requirement was made final.

DISCUSSION

In the petition, Applicants argue that the protein claims, as drawn to a polypeptide having one or more identifying characteristics of SEQ ID No: 10 or a derivative or homologue thereof having the ability to cause apoptosis, should be examined together with the elected nucleic acids, citing Example 17 of Annex B of the PCT administrative instructions. This argument is not persuasive because the pending claims are not in the form presented in the cited example. Example 17 relates to a single protein and the nucleic acids which encode it. The pending claims are not

limited to SEQ ID NO: 10. As noted by the first examiner in the restriction requirement, the specification defines "derivatives" to include fragments, parts, portions, chemical equivalents, mutants and homologues. "Mutant" and "homologue" are not defined in the specification. The second examiner points out in the first action on the merits that the specification does not disclose what portion of SEQ ID NO: 10 causes apoptosis. Thus the claims of Group X are drawn to an ill-defined group of proteins, described chiefly by a functional characteristic rather than a common structure. Since the fact situation is not analogous to Example 17, the conclusion drawn in that example does not apply. Applicants further argue that the prior art cited against claim 1 does not encode a protein similar to SEQ ID NO: 10. This argument is not persuasive. As demonstrated in the discussion above, the claims encompass many nucleic acid sequences encoding proteins which need not be closely related to SEQ ID NO: 10. That the claims as written are not free of the prior art is further evidence that the different groups lack a special technical feature.

Applicants argue that all of the claimed nucleotide sequences should be searched, citing MPEP 803.04. This argument is not persuasive.

MPEP 803.04 states, in part:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten.

Examples of typical nucleotide sequence claims impacted by the partial waiver of 37 CFR 1.141 et seq. (and the partial waiver of 37 CFR 1.475 and 1.499 et seq., see MPEP § 1850) include:

- (A) an isolated and purified DNA fragment comprising DNA having at least 95% identity to a DNA sequence selected from SEQ ID Nos. 1-1,000;
- (B) a combination of DNA fragments comprising SEQ ID Nos. 1-1,000; and
- (C) a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

The pending claims are not limited to claims of the types shown as examples subject to the partial waiver of 37 CFR 1.141, so therefore the exceptions to typical restriction practice set forth in MPEP 803.04 do not apply. Since nucleotide sequences encoding different proteins are recognized as independent and distinct inventions, the restriction requirement is proper.

Applicants argue that Group X should be rejoined with Groups VI-IX. These 5 groups are drawn to proteins. Since applicants have already elected, and received an Office action on, an invention drawn to nucleic acids, this issue is moot.

Applicants argue that restriction of Groups XI-XXII is improper under "the *Ochiai* guidelines." This argument is not persuasive. The Office's practice in view of the *Ochiai* decision is to rejoin

"process of using" claims once a product is found allowable. Restriction is not prohibited. Applicants are referred to MPEP 821.04 for further information on rejoinder of process claims.

DECISION

Applicants's petition is **DENIED** for the reasons set forth above.

The time period for filing a response to the outstanding Office action continues to run from the date of its mailing, August 23, 2002.

Any request for reconsideration or review of this decision must be made by a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely.

Should there be any questions with regard to this letter please contact Bruce Campell by letter addressed to the Director, Technology Center 1600, Washington, DC 20231, or by telephone at (703) 308-4205 or by facsimile transmission at (703) 746-5006.

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